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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing OR ☑ Declaration Submitted After Initial Filing (surcharge (37 CFR 1.16(f)) required)

Attorney Docket Number	
First Named Inventor	Dr. Richard Max Fleming
COMPLETE IF KNOWN	
Application Number	10/603,841
Filing Date	February 26, 2004
Art Unit	1618
Examiner Name	Ebrahim/Hartley

I hereby declare that: (1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention titled:

Dr. Richard Max Fleming, 1697 Lone Oak Trail, Reno, NV 89523
Dr. Gordon M. Harrington, 3720 Village Place, # 6308, Waterloo, Iowa 50702

(Title of the Invention)

the application of which

☐ Is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 02/26/2004 as United States Application Number or PCT International Application Number 10/603,841 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Authorization To Permit Access To Application by Participating Offices

☑ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the World Intellectual Property Office (WIPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified patent application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, WIPO, or other intellectual property office in which a foreign application claiming priority to the above-identified patent application is filed to have access to the above-identified patent application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the above-identified patent application with respect to: 1) the above-identified patent application-as-filed; 2) any foreign application to which the above-identified patent application claims priority under 35 U.S.C. 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified patent application; and 3) any U.S. application-as-filed from which benefit is sought in the above-identified patent application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☑ The address associated with Customer Number: [ ] OR ☐ Correspondence address below

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☑ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any])	Family Name or Surname
Dr. Richard Max	Fleming

Inventor's Signature: D. Richard Max Fleming Date: 14 June 2012

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☐ Additional inventors or a legal representative are being named on the _____ supplemental sheet(s) PTO/SB/02A or 02LR attached hereto

Please find the following responses to the Patent application # 10/603,841 entitled "Method for detecting abnormal tissue using enhanced radiopharmaceutical uptake."

Response to Claim Rejections 35 USC § 112

1 + 2. Claims 17, 19, 34 and 36 rejection. Vascular reactivity means the use of dipyridamole to produce vasodilation to deliver a greater amount of isotope to the metabolically active tissue. Prior doses of dipyridamole did not produce adequate dilatation of vessels did not produce significant changes in delivery of isotope to these metabolically active tissues. These metabolically active tissues vary depending upon mitochondrial concentration and their vascularity. The use of the greater dose of dipyridamole produced a "non-obvious" augmentation of blood flow through the vasculature present at the target site.

3. Claims 17 and 34. The vessels of the target tissues are vasodilated by the 0.852 mg dipyridamole/kg body weight, followed by the injection of technetium-99m isotope, which is quantitatively measured by any device capable of detecting radioactive decay emanating from the target tissue.

Claim Rejections 35 USC § 102

Wilson does not demonstrate what our patent demonstrates. Wilson used a lower dose of dipyridamole and thallium-201, which is not taken up by mitochondria. Wilson concluded that the method was "not reliable enough" to be used. Had the patentee been aware of Wilson's work, it would have been cited. However, the use of a higher dose of dipyridamole produced an exponential increase in tracer activity, which could actually be measure, allowing differentiation from any report by Wilson. Furthermore, the high dose dipyridamole (0.852 mg/kg vs. the 0.56 mg/kg dose of Wilson) was a "non-obvious" difference which when compared by the patentee, demonstrated a "non-obvious" exponential increase in the delivery of isotope not seen before. Additionally, Wilson did not "quantify" findings and therefore cannot statistically differentiate between "normal", "inflammatory" or "cancerous" tissue.

Re: claim 13. Atypia means not typical. It may include "inflammatory" but it means not typical. It cannot be relegated to the term "inflammatory" alone and the patentee is the author of the "Inflammation and Heart Disease" theory not Wilson.

Claim Rejection 35 USC § 103

Block Medical Center should be removed from assignee.
Gordon M. Harrington should be included as co-inventor with Richard M. Fleming

The remainder of this relates to the Crane and Wilson work. Wilsons work and the differentiation between our patent has been discussed supra. Crane and Chiu's work only demonstrate that technetium-99m compounds are taken up by cells through plasma membrane and mitochondrial uptake. There is no work to demonstrate that these authors have investigated the ability to measure this uptake and differentiate between tissue types. The studies demonstrate resting uptake, which like Wilsons standard dose dipyridamole yielded results, which were not diagnostic and ultimately not used. Our patent found the "non-obvious" use of combining high dose dipyridamole with injection of technetium-99m isotopes and then the actual quantification of the decay of the isotope, as well as distinguishing the exact timing of this measurement, having found that measurement at other times did not produce meaningful results. Additionally, our work was compared with mitochondrial differentiation of tissue types. Our results are further supported by the failure of others to develop a quantified system for tissue differentiation, even more than a decade after first submitting this patent for consideration.

3. Again, the use of the term atypia relates to distinguishing different types of tissues. Something, which can only be done by our quantification of B.E.S.T. Here we can do more than just tell you it's not typical. We include all "atypia" including but not limited to mild inflammation, fibrocystic disease, ductal carcinoma in-situ and breast cancer. This distinction is made by isotope measurement.

Dr. Richard Max Fleming

Dr. Gordon M. Harrington

~~14 June~~ 20 July 2012